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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,999	10/04/2005	Hasse Roland Abrahamsson	056291-5214	6477

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EXAMINER	
SPIVACK, PHYLLIS G	
ART UNIT	**PAPER NUMBER**
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/551,999	ABRAHAMSSON ET AL.	
	Examiner	Art Unit	
	Phyllis G. Spivack	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-7 is/are pending in the application.

4a) Of the above claim(s) 5-7 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-4 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 8/4/06
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claims 1-7 are presented and represent all of the claims under consideration.

An Information Disclosure Statement filed August 4, 2006 is further acknowledged and has been reviewed.

The abstract of the disclosure is objected to because it not drawn to the subject matter currently under consideration. Correction is required. See MPEP § 608.01(b).

Claims 5-7 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should only refer to other claims in the alternative. See MPEP § 608.01(n). Accordingly, the claims 5-7 have not been further treated on the merits.

Claims 1 and 3-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

The recitation in claims 1, 3 and 4 "such as man", renders the claims indefinite. It is unclear whether or not claim limitations are intended.

Claims 1 and 4-7 provide for the use of an IBAT inhibitor, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 1 and 4-7 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process

claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2 and 4 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

Claims 1, 2 and 4 recite "or a prodrug thereof" with respect to an IBAT inhibitor. There is insufficient written description for this claim limitation in the disclosure.

> M.P.E.P. § 2163 states, "An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention...one must define a compound by 'whatever characteristics sufficiently distinguish it'. A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process."

The term "prodrug" encompasses a plethora of possible compounds. For example, any chemical compound that is converted into an active curative agent by metabolic processes in the body qualifies as a prodrug in the broadest interpretation of the claims. Further, the structural features of the "prodrug" of an IBAT inhibitor have not been defined. No description of any methods of synthesizing such a broad subgenus of compounds is disclosed.

Accordingly, it is not clear Applicants were in possession of the full scope of the claimed compounds at the time the invention was made. Adequate description requires more than a mere statement that prodrugs are part of the invention. The skilled artisan could not "immediately envisage" the claimed compounds based on the description provided in the disclosure.

Claims 4 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for showing that various benzothiadiazepines treat constipation in an animal model, does not reasonably provide enablement for prevention of constipation from any cause or etiologic factor. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. This is a Scope of Enablement rejection.

To be enabling, the specification must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. *In re Wright*, 27 USPQ 1510 (Fed. Circ.1993). Explaining what is meant by "undue experimentation," the Federal Circuit has stated that:

> The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which experimentation should proceed to enable the determination of how to practice a desired embodiment of the claimed invention. PPG v. Guardian, 75 F.3d 1558, 1564 (Fed. Cir. 1996).

The factors that may be considered in determining whether a disclosure would require undue experimentation are set forth by *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 wherein, citing *Ex parte Forman*, 230 USPQ 546 (Bd. Apls. 1986) at 547,

the court recited eight factors to consider when assessing whether or not a disclosure would require undue experimentation. These factors are:

1) the quantity of experimentation necessary

2) the amount of direction or guidance provided

3) the presence or absence of working examples

4) the nature of the invention

5) the state of the art

6) the relative skill of those in the art

7) the predictability of the art and

8) the breadth of the claims.

These factors are always applied against the background understanding that scope of enablement varies inversely with the degree of unpredictability involved. *In re Fisher*, 57 CCPA 1099, 1108, 427 F.2d 833, 839, 166 USPQ 18, 24 (1970). Keeping that in mind, the Wands factors are relevant to the instant fact situation for the following reasons:

The nature of the invention, state of the prior art, relative skill of those in the art and the predictability of the art

The invention is drawn to the prevention or treatment of constipation. Such characterization encompasses constipation from any etiologic factor.

The relative skill of those in the art is high, generally that of an M.D. or Ph.D. with expertise in the area of gastroenterology.

However, that factor is outweighed by the unpredictable nature of constipation.

The instant specification provides support for the treatment of constipation comprising administering benzothiazepines in an animal model. The disclosure is clearly not predictable for prevention of constipation. The skilled artisan would not reasonably expect that the claimed compounds could be used to prevent any occurrence – under any circumstance - of constipation. A successful treatment modality does not presage success for prophylaxis.

The breadth of the claims

The claims are very broad in that they are inclusive of constipation of diverse etiology.

The amount of direction or guidance provided and the presence or absence of working examples

There are no working examples drawn to preventing constipation. No guidance is provided to distinguish types of constipation to be prevented. Such an assertion is clearly beyond the scope of the instantly claimed invention. The term "prevent" is an absolute definition that means to stop from occurring and thus requires a higher standard for enablement than does "therapeutic" or "treat". It is well established in the medical arts that the vast majority of diseases suffered by mankind cannot be totally prevented with current therapies.

The quantity of experimentation necessary

Applicants have failed to provide guidance as to which particular compound would be preferred for preventing a particular type of constipation that is encompassed in the claim language. The skilled artisan would expect the interaction of a particular

compound in the prevention of a particular type of constipation to be very specific and highly unpredictable absent a clear understanding of the structural and biochemical basis for each agent. The instant specification sets forth no such understanding. Absent reasonable *a priori* expectations of success for using a particular IBAT inhibitor to prevent any particular type of constipation, one skilled in the gastroenterology art would have to test extensively the many IBAT inhibitors that are known in the art to discover which particular type of constipation responds to a particular compound. Since each prospective embodiment, as well as future embodiments as the art progresses, would have to be empirically tested, undue experimentation would be required to practice the invention as it is claimed in its current scope. The specification provides inadequate guidance to do otherwise.

Considering the state of the art as disclosed by the prior art of record, unpredictability of preventing constipation and the lack of guidance provided by the specification commensurate in scope with the claims, one of ordinary skill in the gastroenterology art would be burdened with undue experimentation to treat all forms of constipation comprising administering the instantly claimed IBAT inhibitors. Prevention entails the complete and absolute inhibition of the onset of constipation and any manifestation of the disease entirely.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application

> by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-4 are rejected under 35 U.S.C. 102(e) as being anticipated by Lindquist, A-M, US 2005/0124557.

Lindquist teaches pharmaceutical compositions comprising an IBAT (ileal bile acid transport) inhibitor that may be employed for a laxative effect. See page 19, paragraph [0304], and page 1, paragraph [0005].

Intended use of a composition claim confers no patentable weight to the claim. See *In re Hack*, 114 USPQ 161 (CCPA 1957). Applicant is not entitled to procure claims based on discovery that known compositions can be adapted to new use. To entitle Applicant to patent protection a composition must be both new and unobvious to one skilled in the art.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Ardin Marschel, can be reached 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phyllis Spivack

April 28, 2007

Phyllis G. Spivack
1614

PHYLLIS SPIVACK
PRIMARY EXAMINER